K081438

LifeNet
Saving Lives. Restoring Health

OCT 1 7 2008

510(k) Summary

510(k) Summary in Accordance with 21CFR §807.92

Date Summary Prepared: October 14, 2008

1. 510(k) Owner	LifeNet Health
2. Contact Information	Alyce Linthurst Jones, M.S., RAC Project Manager – LifeNet Health 1864 Concert Drive Virginia Beach, VA 23453 757-609-4359 eFAX: 1-866-813-1302
3. Name of the Device	
Trade Name:	MatrACELL™ Decellularized Pulmonary Artery Patch Allograft
Common Name:	Patches and Pledgets
Classification Name:	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene (21 CFR 870.3470, Product Code DXZ)
4. Predicate Devices	1. CardioFix™ by CarboMedics - K993288 2. CorMatrix Patch for Cardiac Tissue Repair –K063349
5. Device Description	MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is derived from human pulmonary artery tissue and subsequently decellularized. The product is provided in multiple sizes for clinical use.
6. Intended Use of the Device	The MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is indicated for repair of the right ventricular outflow tract..
7. Technological Characteristics	The proposed indications for use for the MatrACELL™ Decellularized Pulmonary Artery Patch Allograft are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is substantially equivalent to the predicate devices.
8. Non-clinical Performance Data	Any differences in technological characteristics between the MatrACELL™ Decellularized Pulmonary Artery Patch Allograft and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the decellularized human pulmonary artery material used in the MatrACELL™ Decellularized Pulmonary Artery Patch Allograft was evaluated through extensive bench and animal testing in the female juvenile sheep model. The collective results have demonstrated that the MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is substantially equivalent to the respective predicate devices with regard to safety and efficacy.
9. Summary	The MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

LifeNet Health
c/o Ms. Alyce Linthurst Jones
Project Manager
1864 Concert Drive
Virginia Beach, VA 23453

Re: K081438
MatrACELL™ Pulmonary Artery Patch Allograft
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: DXZ
Dated: September 12, 2008
Received: September 15, 2008

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LifeNet Health
Saving Lives, Restoring Health

Indications for Use

510(k) Number (if known): _____

Device Name: MatrACELL™ Decellularized Pulmonary Artery Patch Allograft

Indications for Use: The MatrACELL™ Decellularized Pulmonary Artery Patch Allograft is indicated for repair of the right ventricular outflow tract.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031432

(Posted November 13, 2003)

1864 Concert Drive, Virginia Beach, VA 23453 1-757-464-4761 1-757-464-5721 1-800-847-7831 www.lifene